

**ORAL ANTICAVITY- sodium fluoride mouthwash**  
**Amazon.Com Services LLC**

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**Whitening Anticavity Rinse**  
**576.001/576AC**

**Active ingredient**

Sodium fluoride 0.0219% (0.01% w/v fluoride ion)

**Purpose**

Anticavity

**Use**

aids in the prevention of dental cavities

**Warnings**

**Keep out of reach of children**

If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center Right Away

**Directions**

Adults and children 6 years of age and older:

- use twice daily after brushing your teeth with a toothpaste
- vigorously swish 10 mL (2 teaspoonfuls) of rinse between your teeth for 1 minute then spit out
- do not swallow the rinse
- do not eat or drink for 30 minutes after rinsing
- instruct children under 12 years of age in good rinsing habits (to minimize swallowing)
- supervise children as necessary until capable of using without supervision
- children under 6 years of age: consult a dentist or doctor

**Inactive ingredients**

water, glycerin, flavor, cetylpyridinium chloride, sodium saccharin, phosphoric acid, sodium benzoate, sucralose, poloxamer 407, benzoic acid, disodium phosphate, propylene glycol, blue 1

This rinse may cause temporary staining to the surface of teeth. This is not harmful, and adequate brushing may prevent its occurrence.

Sealed with printed neckband for your protection.

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Seattle, WA 98109

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SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION

DO NOT USE IF SAFETY SEAL IS BROKEN OR MISSING.

**PRINCIPAL DISPLAY PANEL**

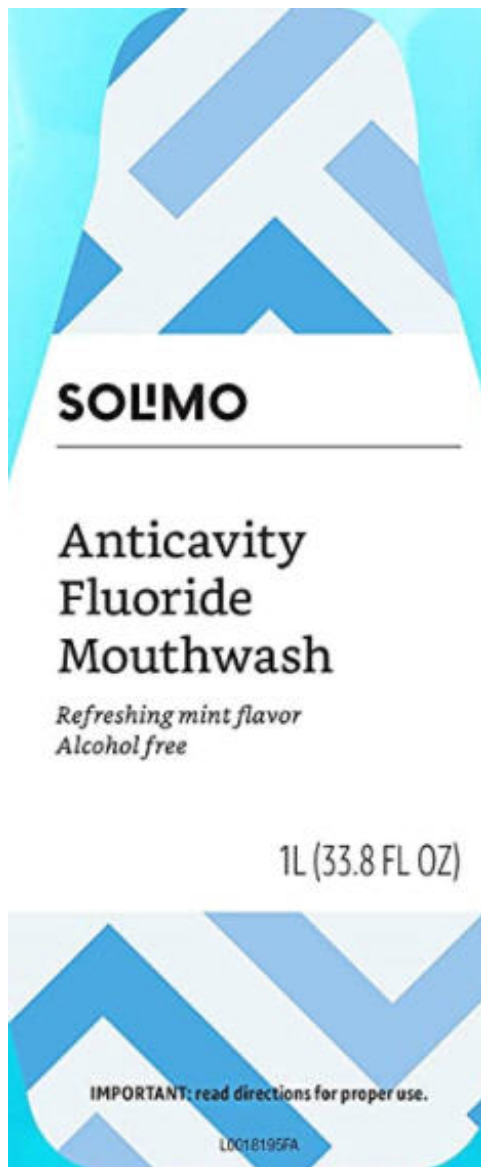
SOLIMO

Anticavity Fluoride Mouthwash

IMPORTANT: READ DIRECTIONS FOR PROPER USE

Refreshing Mint Flavor

1 L (33.8 FL OZ)



## **PRINCIPAL DISPLAY PANEL**

amazon basics

anticavity

fluoride

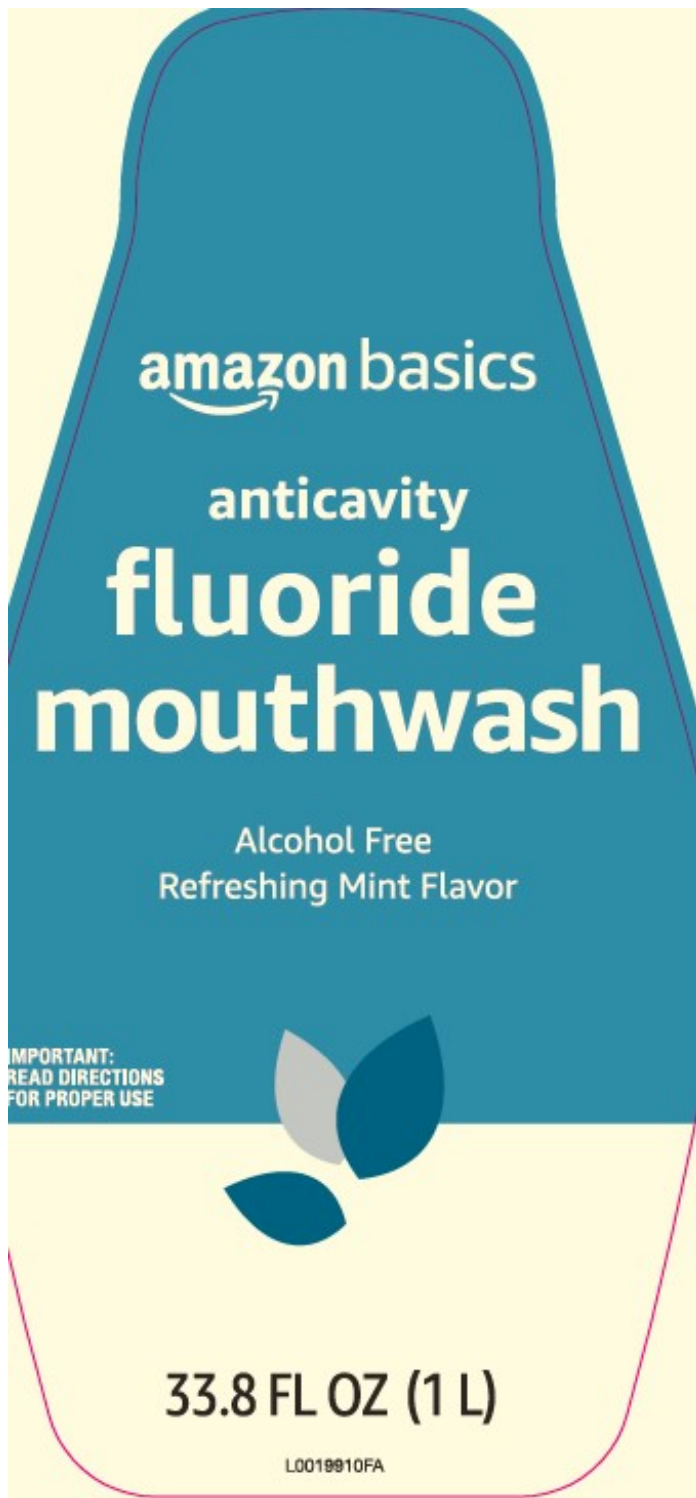
mouthwash

Alcohol Free

Refreshing Mint Flavor

IMPORTANT: READ DIRECTIONS FOR PROPER USE

33.8 fl oz (1 L)



## ORAL ANTIVAVITY

sodium fluoride mouthwash

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72288-576
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	10.41 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>CETYLPIRIDINIUM CHLORIDE</b> (UNII: D9OM4SK49P)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>PHOSPHORIC ACID</b> (UNII: E4GA8884NN)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>POLOXAMER 407</b> (UNII: TUF2IVW3M2)	
<b>BENZOIC ACID</b> (UNII: 8SKN0B0MIM)	
<b>SODIUM PHOSPHATE, DIBASIC, ANHYDROUS</b> (UNII: 22ADO53M6F)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72288-576-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/01/2018	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	05/01/2018	

**Labeler** - Amazon.Com Services LLC (128990418)

**Registrant** - Vi-Jon, LLC (790752542)

### Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(72288-576)

### Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(72288-576)

